UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF TENNESSEE
SOUTHERN DIVISION AT CHATTANOOGA

ANGELA MONTGOMERY, Plaintiff, v. WYETH, f/k/a American Home Products Corp., et al., Defendants.	:	No. 1:05-CV-00323

WYETH'S MEMORANDUM OF LAW IN SUPPORT OF
MOTION TO EXCLUDE OR LIMIT THE TESTIMONY OF KEITH ALTMAN

Wyeth hereby moves to preclude plaintiff's expert Keith Altman ("Mr. Altman") from testifying in this matter under Rule 702 of the Federal Rules of Evidence, Daubert v. Merrell Dow Pharmaceuticals, Inc., 509 U.S. 579 (1993), and Kumho Tire Co. v. Carmichael, 526 U.S. 137 (1998), or in the alternative to limit him to non-expert foundational testimony concerning summaries of evidence under Rule 1006.[1] Plaintiff Angela Montgomery ("plaintiff") claims that she developed primary pulmonary hypertension ("PPH") as a result of her use of Wyeth's prescription anorectic drug Pondimin® (fenfluramine HCI). She has named Mr. Altman, as an expert witness who will testify on her behalf as to certain summaries he created in conjunction with various plaintiffs' counsel in diet drug litigation. As set forth below, Wyeth challenges the admissibility of the testimony and evidence from Mr. Altman on the basis that it does not meet the standards for admissibility set forth in Federal Rule of Evidence 702, Daubert and its progeny.

[1] Wyeth reserves its right to challenge the relevance of these summaries, or the validity of the methodology, by separate motion or at trial.

Mr. Altman, as a self-trained computer technician and plaintiffs' law firm employee, has no expertise relevant to any claim or defense in this case. However, Wyeth anticipates Mr. Altman will be called to testify about Wyeth's internal computer systems and paper files relating to Adverse Drug Event reports ("ADEs") and case reports, case studies, or case series (collectively, "Case Reports") to suggest generally that: (1) Pondimin causes PPH and a separate condition, valvular heart disease ("VHD"), (2) Wyeth had notice of an association between Pondimin and PPH, and (3) Wyeth had notice of an association between Pondimin and VHD. These reports are inadmissible hearsay, are irrelevant to plaintiff's claims, and risk confusing the jury and unduly prejudicing Wyeth.[2] Moreover, Mr. Altman has no expertise in any area of his proposed testimony such that he could give helpful expert testimony.

Pharmaceutical manufacturers create an ADE in their safety surveillance database when they receive specific information that a patient has experienced an "adverse drug event" while taking a prescription drug they manufacture. Under U.S. Food and Drug Administration ("FDA") regulations, an adverse drug event must be created if it occurs near the time the product was used "*whether or not considered drug related*." 21 C.F.R. § 314.80(a) (emphasis added). ADEs and other case reports are merely anecdotal reports describing events and conditions relating to patients, and are based on information that the author may or may not have personally witnessed. It is widely accepted that they do not prove causation. See Conde v. Velsicol Chem. Corp., 804 F. Supp. 972, 1013 (S.D. Ohio 1992) ("[A]necdotal case reports—in which the existence or degree of exposure is unknown or vague, symptoms are self-reported are generally

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[2] The United States District Court for the Eastern District of Missouri recently granted a motion *in limine* in a diet drug case to exclude ADE reports. See Cavender v. American Home Products Corp., No. 02-01830, at 6 (E.D. Mo., June 8, 2007) (order granting motions *in limine*). In Cavender, the court noted that ADEs "are inadmissible hearsay within hearsay, if offered to show causation; are inadmissible unless Plaintiff establishes that ADEs reports are similar to her own alleged injuries; and that ADE reports are not scientifically reliable to prove causation." Id. Wyeth plans to file a similar motion on ADE reports per the scheduling order for filing *in limine* motions.

accepted in the medical/scientific community as, at best, suggestive only.") (internal quotations and citations omitted); see also Saari v. Merck & Co., 961 F. Supp. 387, 398 (N.D.N.Y. 1997) (explaining that an ADE "report to the FDA was simply a report of what plaintiff told [the doctor] about what she believed was her reaction to the vaccine, and by making that report [the doctor] was neither confirming nor denying that there is any relationship between her symptoms and the vaccine").

Mr. Altman has reviewed information he obtained from plaintiffs' lawyers about Wyeth's internal ADE reporting systems and re-organized the information into his own summary format. His expert report, submitted in this case on September 26, 2006, contains no opinions or conclusions on the documents he reviewed, but simply provides an explanation of what documents he reviewed to compile his summaries. Everything he claims to know about the subjects in his expert report he has learned as a litigation consultant for plaintiffs in the diet drug litigation. He takes whatever counsel gives him and performs computer searches on it. The topics that Mr. Altman plans to testify on are irrelevant to any issue in this case and, moreover, his experience as a litigation computer specialist does not provide him with the necessary expertise to give testimony under Federal Rule of Evidence 702, Daubert, and its progeny.[3]

I. FACTUAL BACKGROUND

Plaintiff alleges that Angela Montgomery took the prescription diet medication Pondimin "during 1996 and the first part of 1997" in an effort to lose weight. See Complaint, ¶ 4. Plaintiff further contends that Ms. Montgomery developed PPH due to her use of Pondimin. See id. at ¶ 3. There is no claim that Ms. Montgomery ever had VHD. Thus, the issues in this case are: (1) whether Ms. Montgomery has PPH caused by her alleged use of Pondimin eight years prior to

[3] Nor can Mr. Altman qualify to offer opinion testimony under Federal Rule of Evidence 701 as he is not a percipient fact witness of any events at issue in this case.

her diagnosis; (2) whether the small risk of PPH associated with the use of Pondimin outweighed its benefits; and (3) whether the Pondimin label adequately warned physicians of that risk at the time Ms. Montgomery was prescribed it. Mr. Altman's proposed testimony has little if anything to do with these issues.

II. ARGUMENT AND CITATION OF LEGAL AUTHORITY

A. The Legal Standards For Offering Expert Testimony

Federal Rules of Evidence 401, 402, 403, 702 and 703 provide the basic framework for the admissibility of expert testimony. These principles have been expanded and explained in case law, most notably in Daubert v. Merrell Dow Pharmaceuticals, Inc., 509 U.S. 579 (1993), which set forth the factors to which trial courts should look in determining whether expert testimony is sufficiently reliable to be admitted: (1) whether the theory or technique used by that expert can be or has been tested; (2) whether the theory or technique has been subjected to peer review and publication; (3) the known or potential rate of error of the technique or method; (4) the existence and maintenance of standards and controls; and (5) whether the theory or technique has obtained general acceptance within the scientific community. 509 U.S. at 593-94. Furthermore, the "knowledge" of an expert must be more than personal or subjective belief or "unsupported speculation." Id. at 590.

In Kumho Tire Co. v. Carmichael, 526 U.S. 137 (1999), the Supreme Court put to rest any doubt that the requirements of Daubert and its progeny apply to all expert testimony. Id. at 147. Essentially, to be admissible as expert opinion testimony, the testimony must concern "scientific, technical, or other specialized knowledge" that is beyond the purview of the jury. See Fed. R. Evid. 702. In addition, the testimony must be offered by someone with expertise in the precise area. See Kumho Tire Co., 526 U.S. at 153-58; Fed. R. Evid. 702. Furthermore, the opinions must have resulted from a reliable methodology. See Kumho Tire Co., 526 U.S. at 149-52; Daubert, 509 U.S. at 590-92. Lastly, the opinions must be relevant to the issues in the case

and consistent with the legal standards by which the jury will ultimately judge the evidence. See Daubert, 509 U.S. at 591.

The Sixth Circuit has elaborated on the admissibility requirements as follows:

> The relevance requirement ensures that there is a "fit" between the testimony and the issue to be resolved at trial. See United States v. Bonds, 12 F.3d 540, 555 (6th Cir. 1993). The reliability requirement is designed to focus on the methodology and principles underlying the testimony. See id. at 556.

Greenwell v. Boatwright, 184 F.3d 492, 496-497 (6th Cir. 1999). Testimony that is mere personal belief as to the weight of the evidence is outside the province of the expert. See McGowan v. Cooper Indus., 863 F.2d 1266, 1273 (6th Cir. 1988).

In considering whether expert testimony is sufficiently reliable, and thus admissible, under the Daubert standard, the court should place particular emphasis on whether the expert's research was conducted independent of litigation. Daubert v. Merrell Dow Pharm., Inc., 43 F.3d 1311, 1317 (9th Cir. 1995) ("Daubert II"). As stated in Daubert II, "in determining whether proposed expert testimony amounts to good science, we may not ignore the fact that a scientist's normal workplace is the lab or the field, not the courtroom or the lawyer's office." Id. Similarly, an expert may not simply "parrot" corroborative opinions of other experts, as these opinions are hearsay, and reliance upon them will not necessarily constitute "reasonable reliance." Kim v. Nazarian, 576 N.E.2d 427 (Ill. App. Ct. 1991).

It is the proponent of the proffered testimony who bears the burden of proving its admissibility by a preponderance of the evidence. See Daubert, 509 U.S. at 592 n.10; Cooper v. Smith & Nephew, Inc., 259 F.3d 194, 199 (4th Cir. 2001); 2000 Advisory Notes to Fed. R. Evid. 702.

B. Mr. Altman's Proposed Testimony Is Beyond His Expertise, Irrelevant And Unreliable.

Mr. Altman is a computer technician acting as a litigation consultant to plaintiffs' law firms involved in various mass-tort suits. See Report of Keith L. Altman, 9/26/06, attached

hereto as Exhibit A; Altman Curriculum Vitae, attached hereto as Exhibit B; Deposition of Keith Altman, 3/4/05, at 32, attached in pertinent part at Exhibit C (his activities are "generally connected with plaintiff litigation, yes"). He is employed by Finkelstein & Partners, "a plaintiff's personal injury firm." Altman Dep., Ex. C, at 40. He works solely for plaintiffs in civil cases. Id. at 42-43 ("I've not ever worked for the defense in a personal injury context"). He has an undergraduate degree in astrophysics—a totally irrelevant field—and no further degrees. Altman Curriculum Vitae, Ex. B; Altman Dep., Ex. C, at 53 ("adverse event systems" are "not astrophysics"). Mr. Altman:

- Has no formal education at any level concerning computers except one class, a "tutorial" on an obscure programming language called APL. Deposition of Keith Altman, 10/2/03, at 11, attached in pertinent part at Exhibit D.
- Despite immeasurable advances in computer technology, has taken no computer-related courses in the last eighteen years. Id. at 12 (only computer course, the APL tutorial, was in 1986 or 1987).
- Has never taken any course in mathematical or computer modeling. Altman Dep., Ex. C, at 10 (never taken any data modeling courses).
- Has no degree related to computer science or data processing. Altman Dep., Ex. D, at 9.
- Has no degree in mathematics. Id.
- Has no advanced degrees. Id. (received no further education after college).
- Lacks any graduate or postgraduate education in any relevant field. Id. at 10.[4]
- Has never taught any course, or portion of a course, anywhere. Id. at 52.
- Is not a doctor. Altman Dep., Ex. C, at 55.

All of Mr. Altman's purported "expertise" has come through working for plaintiffs' lawyers. Until becoming involved in diet drug litigation, he "did not" have any experience with

[4] Mr. Altman recently testified that he has recently started taking online classes with an Internet-based correspondence-only law school. Altman Dep., Ex. C, at 40.

"databases used to track ADEs or analyze ADEs." Altman Dep., Ex. D, at 21-22. He has never been an employee of any pharmaceutical company, or done any work directly for such a company. Altman Dep., Ex. C, at 35 (no consulting). He has never worked for the FDA or served on any FDA committee. Altman Dep., Ex. D, at 153.[5]

Mr. Altman submitted an "expert report" in this case on September 26, 2006. See Altman Report, Ex. A. Under the "Conclusion" paragraph of the report, Mr. Altman states:

> I am not an "expert witness" in the sense of C.R. 26, because I will be testifying as to facts, not opinions, although I will use technical expertise to summarize those facts. I have technical expertise to provide summary testimony. This notice allows defendant's sufficient time to cross-examine me on my findings and summaries. The summaries linked to the original images of documents, complete with AHP bates numbers, are available in the office of plaintiff's counsel upon reasonable notice.

Id. at 5. Mr. Altman claims he has reviewed certain electronic data from Wyeth's internal computer system called the Clinical Data Safety Surveillance System ("CDSSS") and the S^3 system that contains the electronic versions of Wyeth's ADEs on Pondimin and Redux. Id. at 3. He also reviewed paper files on certain ADEs. Id. At no time within Mr. Altman's report does he provide an actual conclusion from his work—only that he reviewed documentation related to ADEs. As stated above, and in Mr. Altman's own words, he is "not an 'expert witness'." However, there is no provision within the Federal Rules for testimony before the jury from a witness who is neither possessed of personal knowledge of relevant facts nor offering opinions

[5] He claims only that on one occasion the Agency accepted his unsolicited advice. Altman Dep., Ex. C, at 39.

based on relevant expertise and a reliable methodology. There is no "other" category into which Mr. Altman can be fit and permitted to testify. He is essentially a non-witness.[6]

Mr. Altman's report reflects the confusion evident at his latest deposition, when he claimed not to know if he was an expert witness or not. Altman Dep., Ex. C, at 5 ("I'm not exactly sure exactly what capacity I was named in"; "I don't know whether I'm being deposed as an expert"). Mr. Altman had difficulty with the very concept of an opinion:

> Q. Do you know what opinions are?
>
> A. I mean are you asking me am I going to – I don't think I'm going to express particular opinions about [the plaintiff] or anything like that. I may. . . say what the data says or how the data was put together was things like that. If you want to call that an opinion or an observation, I don't know. I guess that's a definitional issue.

Id. at 6. Mr. Altman denies having any opinions about either plaintiffs or Wyeth. Id. (as to individual plaintiff); 7 (as to Wyeth). It is not his "job" to have opinions about causation or warnings. Id. at 66. Mr. Altman does not purport to "interpret" any ADE. Id. at 7 ("I don't expect to interpret those reports"), 67. He is "not being offered" to discuss "what any of the information in any ADE means." Id. at 7-8. Indeed, he is not even going to offer opinions about the adequacy of Wyeth's data management:

> Q. Do you intend to talk about the adequacy of the CDSSS or the SQ [cubed] systems?
>
> A. I don't think I'll be doing that at this time.

Id. at 9.

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[6] If plaintiff merely intends to offer Mr. Altman as a witness before the Court on any Rule 104 proceedings to support the admissibility of a summary chart under rule 1006, then Wyeth has no objection provided that it can cross-examine Mr. Altman at such a proceeding.

As a litigation consultant, the "reports" Mr. Altman produces are "run at the request of attorneys," as is all other ADE-related "work" he has done. Id. at 12. Mr. Altman does not even look at the underlying ADEs. Id. at 90. ("Q. Have you looked at the underlying reports? A. No."), id. ("I have not looked at the underlying reports"), 126 ("Q . . .[Y]ou did not attempt to review the underlying reports for any substance? A. No.").

Mr. Altman does not interpret his results, " leav[ing] it up to the medical or scientific experts to draw any opinions from their review of" his reports. Id. at 66.

> [T]hat's for some expert to decide what the meaning of this is. All I did was present a report of what's in the database that says valve replacement surgery.

Id. at 148.

> Q. To have any opinions about whether any of these numbers in the database mean anything, you expect the expert to do additional review, don't you?
>
> A. I expect the expert to do whatever they deem is appropriate. I don't know whether that means additional review or not. That's – they're the expert who's testifying.

Id. at 68; see also id. at 150 ("I provided what the database shows. Some other expert, it's their role to decide what that means.").

Mr. Altman prepares his reports on VHD with "no idea how [Wyeth] used the term valvular heart disease" thus including ADEs that do not have clinically significant levels of regurgitation. Id. at 100, 108-109, 173. He operates with no exclusion criteria at all. Id. at 176 ("Q. And you obviously . . . didn't have any exclusion criteria, did you? A. No."). Instead, he uses whatever is in a database supplied by counsel, making no effort to understand how or why any of the ADEs were created. Id. at 79 ("That's the database that was provided. If it's in there, it's in there. If it's not, it's not"); 90 ("The database is what the database shows"); 157 ("I can only go by what's in your database"). Over and over again, Mr. Altman displays rote,

unthinking acceptance of whatever data he is given. See id. at 72:1-6, 73:20-24, 74:18-75:23, 79:24-80:8, 88:15-21, 89:10-19, 91:1-21, 101:7-102:1, 103:5-11, 103:19-23, 132:20-133:5, 136:12-22, 140:13-141:9, 142:13-143:4, 145:6-11; 148:10-23, 154:25-155:9, 155:22-156:16, 157:23-158:4; 159:4-20, 168:10-21, 179:4-11, 180:23-181:10, 183:21-184:9, 197:5-10. For instance, Mr. Altman does nothing to eliminate duplicate ADEs or ADEs resulting from a lawsuit. Id. at 29-32.

1. Mr. Altman's Testimony Concerning ADEs is Irrelevant.

Mr. Altman's testimony concerning ADEs should be excluded wholesale because the ADEs themselves are irrelevant to any issue in this case. Mr. Altman purports to testify about nothing else.

ADEs are merely anecdotal reports with no statistical validity. Counting ADEs as Mr. Altman does, without the ability to do any other analysis, is a pointless exercise as the reporting frequency of ADEs is greatly influenced by extraneous factors such as "publicity" and "litigation." Altman Dep., Ex. C, at 25-27. Thus, his summaries are no more admissible than individual ADEs, which are widely held to have extremely limited admissibility.

Numerous state and federal decisions support the proposition that ADEs are not probative of any issue of causation. ADEs "make little attempt to screen out alternative causes for a patient's condition," and "frequently lack analysis." Glastetter v. Novartis Pharms. Corp., 252 F.3d 986, 989-90 (8th Cir. 2001) (affirming exclusion). In Reynolds v. Warthan, 896 S.W.2d 823 (Tex. App. 1995), the court held that ADEs were irrelevant and misleading on issues of causation and risk. The court followed the FDA's expressed views, id. at 827-28, and determined that ADEs failed to "establish a causal link" between the drug and alleged injuries but instead "created a suspicion without any medical proof." Id. at 828. The court in Soldo v. Sandoz Pharms. Corp., 244 F. Supp. 2d 434, 537 (W.D. Pa. 2003), held that "because the [FDA]

case reports themselves say that causation has not been proven, reliance on the case reports is *per se* unscientific."

> ADEs do not demonstrate a causal link but instead represent coincidence. Case reports and ADEs are compilations of occurrences, and have been rejected as reliable scientific evidence supporting expert opinion . . . Unlike epidemiological studies, they do not contain a testable and systemic inquiry into the mechanism of causation. As such, they reflect reported data, not scientific methodology.

Id. at 537-38 (excluding expert opinions based on ADEs) (citations and quotation marks omitted). Precedent supporting the proposition that ADEs have no place in establishing causation in personal injury cases is overwhelming.[7]

The only possible use of ADEs is, through otherwise admissible testimony, to attempt to establish notice of a risk of the condition that plaintiff claims. To the extent notice is even an issue in this case—Pondimin's label warned of a risk of PPH when plaintiff was prescribed it—

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[7]See Rider v. Sandoz Pharms. Corp., 295 F.3d 1194, 1199 (11th Cir. 2002) (ADEs "are merely accounts of medical events" and "reflect only reported data, not scientific methodology"); Hollander v. Sandoz Pharms. Corp., 289 F.3d 1193, 1211 (10th Cir. 2002) (ADEs "contain only limited information" and are "unreliable evidence of causation"); Dunn v. Sandoz Pharms. Corp., 275 F. Supp. 2d 672, 682 (M.D.N.C. 2003) (ADEs "are not scientific proof of causation"); Cloud v. Pfizer, Inc., 198 F. Supp. 2d 1118, 1133-34 (D. Ariz. 2001) (ADEs "are merely compilations of occurrences, and have been rejected as reliable scientific evidence supporting an expert opinion"); Caraker v. Sandoz Pharms. Corp., 172 F. Supp. 2d 1046, 1050 (S.D. Ill. 2001) (ADEs "make little attempt to isolate or exclude possible alternative causes, lack adequate controls, and lack any real analysis"); Brumbaugh v. Sandoz Pharm. Corp., 77 F. Supp. 2d 1153, 1156-57 (D. Mont. 1999) ("most significant analytical defect [of ADEs] is that they don't isolate and investigate the effects of alternative causation"); Haggerty v. Upjohn Co., 950 F. Supp. 1160, 1164 (S.D. Fla. 1996) (ADEs "contain raw information that has not been scientifically or otherwise verified as to cause and effect" and cannot be a basis for expert testimony); Wade-Greaux v. Whitehall Labs., Inc., 874 F. Supp. 1441, 1481 (D.V.I. 1994) ("such data represent anecdotal information of chance associations, do not purport to assess cause and effect and have no epidemiological significance"); Conde v. Velsicol Chem. Corp., 804 F. Supp. 972, 1013 (S.D. Ohio 1992) ("[A]necdotal case reports—in which the existence or degree of exposure is unknown or vague, symptoms are self-reported are generally accepted in the medical/scientific community as, at best, suggestive only.").

the case law requires foundational testimony to establish similar circumstances between the ADEs at issue and the facts of the case. See e.g., Cavender v. American Home Products, Corp., No-02-01830 (E.D. Mo. June 8, 2007); Rye v. Black & Decker Mfg. Co., 889 F.2d 100, 102-103 (6th Cir. 1989). Because Mr. Altman has no medical or scientific expertise, has no personal knowledge of any of the ADEs, and has no personal knowledge of the facts here, he cannot begin to establish foundation for the use of any ADEs for notice. As such, any testimony he could give about ADEs would be irrelevant and inadmissible.

2. Mr. Altman Cannot Testify to the Meaning of Fields in the CDSSS Database.

Mr. Altman has done nothing more than summarize portions of documents provided to him by lawyers. Before becoming a litigation consultant, he knew nothing about the FDA, Wyeth, Pondimin, or any other relevant topic. "Expertise" of the sort required by Daubert simply cannot be manufactured out of whole cloth during the course of litigation.

Mr. Altman's report indicates that using "accepted technical principles and methodology … [he was able to] determine the meaning of the fields in the [CDSSS] database (attached in the CD-Rom) as well as the relationship between the various tables." Altman Report at 4, Ex. A. Though plaintiff frames this activity on the part of Mr. Altman in the language of expert analysis, such framing could not be more misleading as to the actual nature of Mr. Altman's work. Mr. Altman essentially concedes that no "scientific principles" were necessary to determine the meaning of the fields in the CDSSS database. By his own admission, no expertise was involved in the task that he claims to have successfully performed with regard to the CDSSS:

> Q. You don't have anything saying that your technique is the generally accepted technique or the industry standard?
>
> A. I mean that's a little bit like saying that I don't have a document that says that ten over two equal five. All I did was load

> the stuff into Microsoft Access and work with it. I mean it's routine every single day kind of stuff.

Altman Dep., Ex. C, at 69-70. Mr. Altman also has indicated that to the extent he purports to have analyzed data from the FDA, no expert analysis was involved in his actions:

> Q. "5. Any documents that purport to explain Mr. Altman's tools for analyzing the adverse event data made available by the FDA."
>
> A. It is a tool. FDA provides the data and *it speaks for itself*. They describe what the tables are and what the columns are, and I have provided to you the complete set of FDA adverse event data.

Id. at 69 (emphasis added).

Mr. Altman's statements emphasize the extent to which he is simply a layman attempting to organize data. He is wholly lacking in expertise that could "assist the trier of fact to understand or determine a fact in issue." Daubert, 509 U.S. 579 (1993). Not surprisingly, given his lack of expertise and the non-expert witness nature of his testimony, by Mr. Altman's own admission he has not followed any scientific methodology in arriving at any opinions, indeed he disclaims opinions. Mr. Altman's testimony related to the CDSSS should be excluded.

3. Mr. Altman Cannot Testify to the Relationship Between the Various Tables.

Mr. Altman's report also evinces an intent by the plaintiffs to offer Mr. Altman's testimony for the purpose of opining on "the relationship between the various tables" in the CDSSS. Altman Report at 4, Ex. A. Mr. Altman has no expertise in any of the areas necessary for him to make such an assessment and he employs no reliable methodology. Accordingly, his testimony in this regard must be excluded.

In order to offer an opinion on the relationship between various tables' in Wyeth's or the FDA's data, Mr. Altman would minimally need either experience in adverse event reporting or the pharmaceutical industry in general. Mr. Altman possesses neither. As mentioned above, he

has never been an employee of any pharmaceutical company. Altman Dep., Ex. C, at 14-15 (never been a direct employee of any pharmaceutical company). None of the data sets Mr. Altman worked with during his education ever involved adverse drug experiences. Id. at 14 (none of the data sets worked with involved ADEs). He has not taken any courses on adverse drug experiences, adverse drug experience reporting, or the maintenance of databases by the FDA or drug companies. Id. at 15. Prior to working for plaintiffs in the diet drug litigation, Mr. Altman had no experience working with databases relating to adverse drug experience reports. Id. at 21-22 (working with databases relating to adverse drug experience reports was new experience). Though his report suggests that he will offer an opinion on it, Mr. Altman has conceded his lack of expertise with regard to the way the FDA maintains its adverse drug event database:

> Q. Do you claim expertise in the way the FDA maintains its database on ADEs?
>
> A. Only to the extent of what they make available to the consuming public.
>
> Q. You don't know about how they deal with it behind closed door?
>
> A. I do have knowledge, but *I don't know that I'd necessarily be an expert*.

Id. at 26 (emphasis added). At the time that he was retained by plaintiffs, Mr. Altman had done no work of any kind regarding ADEs for a drug company. Id. at 30.

Mr. Altman also fails to employ a reliable methodology in arriving at his opinion on "the relationship between the various tables" in the CDSSS. The primary work product of Mr. Altman's relationship with plaintiffs is a set of spreadsheets that purport to explain the data in the CDSSS. Altman Report at 4-5, Ex. A. However, Mr. Altman has used no "scientific, technical, or other specialized knowledge" in arriving at his conclusions. He asserts that he is using

"common sense meaning that anybody would take them to mean," in arriving at his conclusions about the relationships between the various tables. Altman Dep., Ex. C, at 61. This is the antithesis of what is required under the Federal Rules for expert opinion to be admitted under Daubert. Mr. Altman concedes that nothing in his methodology allows him to assert the accuracy of the spreadsheets that he purports to have created:

> Q. You can't testify to the accuracy of the individual pieces of data within in the fields?
>
> A. That is absolutely true. I can only say what I see.
>
> * * * *
>
> Q. You're not relying on any specific medical expertise or regulatory expertise that you think you hold that you interpret any of the information within any of the boxes on Exhibits Two, Three, Four or Five?
>
> A. I'm not interpreting anything. I'm providing a compilation of what I see in the data.

Id. at 61. Mr. Altman further concedes that he cannot verify several of the tables within the spreadsheets that he allegedly created. Id. at 65. When asked to produce "Any article or scholarly paper supporting Mr. Altman's methodology for determining the relationship between various tables and adverse event files," Mr. Altman could only respond "No. No such documents." Id. at 70-71. Mr. Altman's methodology falls far short of what is required for admission of expert testimony under Daubert. His testimony on the relationship between the various tables in the CDSSS should be excluded.

4. Mr. Altman's Testimony on Valvular Heart Disease is Irrelevant

Several documents listed in Mr. Altman's report relate to valvular heart disease ("VHD").[8] Plaintiff only claims PPH as an injury here, not VHD. See Complaint at ¶ 3. At no time has plaintiff claimed VHD as an injury. Therefore, any testimony or references to VHD in this case are completely irrelevant. A court in this Circuit has recognized that the only relevant evidence in a product liability case involving prescription drugs is evidence relating to the disease the plaintiff claims she contracted as a result of taking the medication. See Bouchard v. American Home Prods., 213 F. Supp.2d 802, 810-811 (N.D. Ohio 2002) (holding, in a Redux VHD case, evidence of PPH excluded as plaintiff's claim not based on that condition). VHD evidence has no tendency to make the existence of any fact that is of consequence to this PPH case more probable or less probable than it would be without such evidence. Injecting VHD at trial would only serve to confuse the jury and prolong trial. Accordingly, as Wyeth will request in a motion *in limine*, all VHD evidence should be excluded at trial and Mr. Altman's proposed testimony on VHD must be excluded because it concerns subjects that are neither relevant or admissible under Rules 401, 403 and 702.

III. CONCLUSION

For all the reasons stated above, Wyeth respectfully requests this Court enter an order excluding or limiting the opinion of Mr. Keith Altman.

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[8] See e.g., Altman Report at 4-5, Ex. A (4195A – VHD Reports; 4195B – VHD Reports with PH; 4195E – VHD Reports 9/15/97-8/99; 4195F – VHD Reports 9/15/97-8/99; 4195G – Post Withdrawal Reports of Aortic Valve Surgery; 4195H – Post Withdrawal Reports of Mitral or Unspecified Valve Surgery; 4195I – Mitral and Aortic Valve Surgery Reports after 10/1/99; 4195K – Reports With Valve Surgery Indicated After 10/1/99; 4195M 0- VHD Reports of 15-60 Days Duration with Pondimin and Redux).

Respectfully submitted,

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Dated: December 17, 2007

CERTIFICATE OF SERVICE

I HEREBY CERTIFY that on this 17th day of December 2007, I electronically served a copy of the foregoing Wyeth's Memorandum of Law in Support of Motion to Exclude or Limit the Testimony of Keith Altman, to the following:

Gregory F. Coleman
Coleman & Edwards
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Gregory J. Bubalo
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/s/ Samuel L. Felker
Samuel L. Felker